NDI Medical

NeuroStim Innovations to Market

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Federal Communication Commission

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Comments on the Proposed Rule Changes relating to the use of implanted and body-worn medical transmitters in the 400 MHz band.

Ladies and Gentlemen:

NDI Medical is a medical device developer and manufacturer active in the area of neurostimulation and implantable neurostimulation devices for therapeutic and functional restoration applications. In this context, we would like to comment on the proposed rule changes relating to the "MedRadio" service.

Overview of Need for Wireless Spectrum for Implantable and Body Worn Devices

The rapid advancement of electro-medical devices and therapies to treat or mitigate the effects of injury or disease and to restore function or quality of life is obvious throughout the United States and the world. Many of these devices are used by patients on a permanent basis or for long periods of time. Many of these devices are implantable; or have elements that are implanted. The quality of life for hundreds of thousands of Americans have been improved by implantable pacemakers, cardio-defibrillators, cochlear prostheses, Vagal Nerve stimulators, and deep brain stimulators.

As the technology continues to advance, many more applications will be found for implantable devices. Many of these new applications will require the implantable devices communicate through short-range RF links with body worn or very nearby accessory devices. In many of these applications, the patient will use body worn or hand carried devices to generate commands that are wirelessly communicated to their implanted device. In some applications, patient invoked commands might be generated at a low rate; e.g. occasional adjustments to the intensity or area of stimulation of a neuromodulation device. In other applications, the patient may invoke no commands for long periods of time, and then invoke many commands every second for a periods of several minutes; e.g., a Functional Electrical Stimulation device that restores function to a paralyzed hand, arm, or leg.

NDI Medical and other innovative medical device companies are developing implantable neurostimulation devices for such therapeutic and function restoration applications. We see great potential for such devices to improve the lives of countless thousands of people in American and throughout the world. It is in that context that we encourage the FCC's actions at expanding the availability and usability of radio communications spectrum for these ultra-low power applications.

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Specific Comments:

- The FCC proposal to “add the 401-402 MHz and 405-406 MHz ("wing bands") to the existing MICS allocation”; and to permit “these body-worn and implant transmitters having low-power and low duty cycles to operate without frequency monitoring capability” is a good and appropriate allocation of spectrum. The rationale is appropriate and we are aware of no significant concerns raised by such a revision to the rules.

- The FCC proposal to “maintain the existing MICS rules in this spectrum, and continue to license use of MICS devices by rule” is also a good decision. This decision ensures that there is an appropriate allocation and a mechanism for sharing the spectrum for those devices with more complex, and typically higher total data transfer, needs.

- We encourage the FCC to maintain the specific “Frequency Monitoring” requirements currently encompassed in 95.628 (a). These requirements establish the basis for non-interference without imposing a specific remedy. For example, a frequency agile device may use that method to transmit avoid interfering with other users. Similarly, a device that is not frequency agile must wait for the spectrum to be unused before transmitting.

- We encourage the FCC to be aware that these implantable and body worn medical devices need to operate (and communicate) in a variety of environments and locations; not just in a clinical setting.

We support the FCC’s actions at expanding the availability and usability of radio communications spectrum for the “MedRadio” service. These ultra-low power applications are becoming increasingly important and life improving. Actions to make these devices more effective and functional will have a beneficial effect on the health of the Americans for a long time to come.

Sincerely yours,

Robert B. Strother, Jr. VP of Engineering
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